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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,150	07/25/2001	Gary R. DelDuca	47097-01080	6442

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EXAMINER
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MADSEN, ROBERT A

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/915,150

Applicant(s)

DELDUCA ET AL.

Examiner

Robert Madsen

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 and 87-189 is/are pending in the application.
- 4a) Of the above claim(s) 91-160 and 172-189 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed. AND 161-171
- 6) ☒ Claim(s) 1-37 and 87-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. The Amendment filed September 8, 2003 has been entered. Claims 38-86 have been cancelled and claims 87-189 have been added.
2. The rejections of claims 1-37 made under 35 USC 103(a) in the office action mailed May 7, 2003 stand for the reasons of record, and have been copied into this office action to address new claims 87-90.
3. Newly submitted claims 91-160, 172-189 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
4. The elected claims 1-37, and as well as new claims 87-90, 161-171, are drawn to a method of wrapping a first package having a non-barrier oxygen *permeable* portion and containing meat with a substantially *impermeable* second package and filling the pocket formed between the two packages with a mixture of gases.
5. The invention of claims 91-122 is drawn to substantially *removing* meat from an *impermeable* first package containing a modified atmosphere and *placing* the meat into a second package having a non-barrier, oxygen permeable portion. Thus, the invention of claims 91-122 is distinct from the originally presented claims 1-37 because it has a different mode of operation since (1) the meat is held in a substantially *impermeable*, (2) the meat is removed from a first package and placed in a second package, and (3) the first meat package is not wrapped by a second package.
6. The invention of claims 123-160, 172-189 is drawn to a method of placing meat in a first package having a non-barrier oxygen *permeable* portion, *wrapping* the first package, and covering the first package with a substantially *impermeable* second

package and filling the pocket formed between the two packages with a mixture of gases. This invention is distinct from the invention of the originally presented claims 1-37 because it has a different mode of operation because there are actually three packages: the first package, the wrapper, and the second package wherein the wrapper could be either outside of the second package or between the two package.

Additionally, it is noted that with a first package comprising an overwrap (in dependent claims), any additional *wrapping* step (as recited in the independent claim) is not supported by applicant's specification. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 91-160, 172-189 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03..

### ***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1,5,6,9-11,16-18,20-22,25,26,29-30,35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorheim et al. (Meat Science 1999) in view of Colombo (US 6112890).

9. Sorheim et al. teach adding CO to modified atmosphere meat packages to maintain a red color as an improvement over conventional high oxygen modified atmosphere meat packages or low oxygen with oxygen scavenger packages for

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sale/consumption. Sorheim et al. teach 0.3-0.5% CO, along with 60-70% CO<sub>2</sub>, 30-40% N<sub>2</sub>, and 0% O<sub>2</sub> to form carboxymyoglobin from oxymyoglobin, which would have formed after the 2 hr. delay in grinding/cutting wherein the oxygen is removed from the package so that initially the level is less than 0.5% and within 2-3 days it is about zero (Page 157, 2.2 on 158, Table 1 on page 160, 4.3 on Page 163), as recited in claims 1, 5, 6, 9-11, 18, 20, 21, 22, 25, 26, 29-30, 36, 37, 87-90. However, Sorheim et al. are silent in teaching a method of packaging comprising two packages as recited in claims 1 and 22.

10. Colombo is relied on as evidence of a conventional modified atmosphere meat package comprising an oxygen scavenger wherein a first package comprising a polystyrene foam tray sealed by a pvc overwrap is contained within a second package that is a barrier film and forms a pocket (Example 1, Figures), as recited in claims 1, 16, 17, 22, 35.

11. Therefore, it would have been obvious to modify the method of Sorheim et al. and include a first package comprising a polystyrene foam tray sealed by a pvc overwrap is contained within a second package that is a barrier film and forms a pocket, since Colombo teaches this meat package is for use with modified atmospheres utilizing oxygen scavengers and Sorheim et al. teach adding carbon monoxide to a low oxygen gas mixtures will better preserve the meat than adding an oxygen scavenger to a gas mixture.

12. Claims 12 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorheim et al. (Meat Science 1999) in view of Colombo (US 6112890), as applied

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to claims 1,5,6,9-12,16-18,20-22,25,26,29-30,35-37, further in view of Verbruggen(DE1935566).

13. Sorheim et al. are silent in teaching just CO and CO<sub>2</sub> in the modified atmosphere. However, Verbruggen teaches preserving meat color with carbon dioxide and carbon monoxide after vacuum treatment (English Abstract). Therefore it would have been obvious to include only CO and CO<sub>2</sub> since one would have been substituting one modified atmosphere composition for another for the same purpose.

14. Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sorheim et al. (Meat Science 1999) in view of Colombo (US 6112890), as applied to claims 1,5,6,9-12,16-18,20-22,25,26,29-30,35-37, further in view of Woodruff et al. (US 4522835).

15. Sorheim et al. are silent in teaching converting oxymyoglobin to deoxymyoglobin first and then to carboxymyoglobin.

16. Woodruff et al. teach treating storing meat in a reduced oxygen modified atmosphere of 0.1-3% CO, along with 20-60% CO<sub>2</sub>, 40-80% N<sub>2</sub>, and 0% O<sub>2</sub> and convert deoxymyoglobin to carboxymyoglobin on the surface of the meat. Woodruff et al. teach meat that is stored in a refrigerated or frozen state under low oxygen conditions prior to final sale/consumption packaging. Woodruff et al. teach removing the O<sub>2</sub> causes the meat to turn purple and Woodruff et al. returns the red color after storage by adding carbon monoxide (Abstract, Column 1, line 63 to Column 3, line 30, Examples). Therefore, to oxymyoglobin to deoxymyoglobin first and then to

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carboxymyoglobin would have been an obvious matter of choice, depending on if one is to store the meat prior to final packaging..

17. Claims 1-11,13-15,18, 20-30,32-34,36,37,87-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorheim et al. (Meat Science 1999) in view of Breen et al. (US 5711978).

18. Sorheim et al. teach adding CO to modified atmosphere meat packages to maintain a red color as an improvement over conventional high CO<sub>2</sub> atmospheres for sale/consumption. Sorheim et al. teach 0.3-0.5% CO, along with 60-70% CO<sub>2</sub>, 30-40% N<sub>2</sub>, and 0% O<sub>2</sub> to form carboxymyoglobin from oxymyoglobin, which would have formed after the 2 hr. delay in grinding/cutting wherein the oxygen is removed from the package so that initially the level is less than 0.5% and within 2-3 days it is about zero(Page 157,2.2 on 158, Table 1 on page 160, 4.3 on Page 163),as recited in claims 1,5,6,9-11,18,20,21,22,25,26,29-30,36,37. However, Sorheim et al. are silent in teaching a method of packaging comprising two packages as recited in claims 1 and 22.

19. Breen et al. teach the conventional high carbon dioxide modified atmosphere meat overwrapped meat tray for sale/consumption. Breen et al. teach supplying a first package comprising a sealed tray, surrounding the tray with a bag, wherein at least a portion of bag can be removed for retailing without destroying the tray to expose the meat to ambient atmosphere, removing oxygen by vacuum and supplying/flushing a mixture of gases into the bag, and sealing the bag. As an extra measure of safety, Breen et al. further teach adding an oxygen scavenger in the pocket. Additionally Breen

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et al. teach the oxygen content is 30-50 ppm just after sealing the bag (Figure 7, Column 2, lines 27-62, Column 5, lines 33-55 ) as recited in claims 1-3, 5-8,13-15,22-28,32-34,87-90 Therefore, it would have been obvious to modify the method of Sorheim et al. and include a first package comprising surrounding the tray with a bag, wherein the at least a portion of the bag can be removed for retailing without destroying the tray to expose the raw meat to ambient atmosphere, removing oxygen by vacuum and supplying/flushing a mixture of gases into the bag, such that 30-50 ppm remain between the bag and tray, and sealing the bag, since this is a conventional method of packaging using a high carbon dioxide modified atmosphere and Sorheim et al. teach an improvement over this method by including carbon monoxide. It would have been further obvious to include an oxygen scavenger since Been et al. teach this is an extra measure of safety for removing oxygen. Breen et al. further teach adding an oxygen scavenger in the pocket.

20. Regarding claim 4, Sorheim et al. are silent in teaching any particular level of oxygen after 24 hours. However, Been et al. teach evacuating and flushing to achieve 30-50 ppm in the pocket that stabilizes to 250 ppm (the concentration in the tray) within 2-3 minutes and drops off significantly as it is absorbed by the meat (Column 5, lines 41-55). Therefore, it would have obvious that in 24 hours one would have virtually no oxygen since Been et al. teach the one may also add a scavenger, which would only reduce the oxygen level of 250 ppm faster.

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21. Claims 12 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorheim et al. (Meat Science 1999) in view of Breen et al. (US 5711978), as applied to claims 1-11,13-15,18,20-30,32-34,36,37,87-90 above, further in view of Verbruggen(DE1935566).

22. Sorheim et al. are silent in teaching just CO and CO<sub>2</sub> in the modified atmosphere. However, Verbruggen teaches preserving meat color with carbon dioxide and carbon monoxide after vacuum treatment (English Abstract). Therefore it would have been obvious to include only CO and CO<sub>2</sub> since one would have been substituting one modified atmosphere composition for another for the same purpose.

23. Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sorheim et al. (Meat Science 1999) in view of Breen et al. (US 5711978), as applied to claims 1-11,13-15,18, 20-30,32-34,36,37,87-90 above, further in view of Woodruff et al. (US 4522835).

24. Sorheim et al. are silent in teaching converting oxymyoglobin to deoxymyoglobin first and then to carboxymyoglobin.

25. Woodruff et al. teach treating storing meat in a reduced oxygen modified atmosphere of 0.1-3% CO, along with 20-60% CO<sub>2</sub>, 40-80% N<sub>2</sub>, and 0% O<sub>2</sub> and convert deoxymyoglobin to carboxymyoglobin on the surface of the meat. Woodruff et al. teach meat that is stored in a refrigerated or frozen state under low oxygen conditions prior to final sale/consumption packaging. Woodruff et al. teach removing the O<sub>2</sub> causes the meat to turn purple and Woodruff et al. returns the red color after

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storage by adding carbon monoxide (Abstract, Column 1, line 63 to Column 3, line 30, Examples). Therefore, to oxymyoglobin to deoxymyoglobin first and then to carboxymyoglobin would have been an obvious matter of choice, depending on if one is to store the meat prior to final packaging.

26. Claims 161-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over DelDuca et al. (US 5698250) in view of Sorheim et al. (1999) or Woodruff et al. (US 4522835).

27. DelDuca et al. teach a method of manufacturing a modified atmosphere package comprising: placing a retail cut of raw meat in a first package with a non-barrier portion substantially permeable to oxygen, wrapping the package with PVC overwrap, covering the first package with a second substantially oxygen impermeable package to create a pocket between the packages, supplying a gas mixture into the pocket, removing oxygen from the pocket to sufficiently reduce an oxygen level to inhibit or prevent metmyoglobin formation on the surface of the raw mea, as recited in claim 161, and further including an oxygen scavenger as recited in claim 162, removing the oxygen by flushing the pocket with a mixture consisting essentially of nitrogen and carbon dioxide as recited in claims 164-166, removing the second package to modify the atmosphere to expose the meat to ambient and for display without destroying the first package such that the raw meat has a color of fresh cut meat as recited in claims 167-171 (See Abstract, Column 1, lines 55-60, Column 2, lines 23-56, Column 3, lines 32-35, 54-59, Column 4, lines 45-58).

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28. DelDuca et al. however, are silent in teaching using any carbon monoxide.

Sorheim et al. teach adding CO to modified atmosphere meat packages to maintain a red color as an improvement over conventional high CO<sub>2</sub> atmospheres for sale/consumption.

29. Sorheim et al. teach adding CO to modified atmosphere meat packages to maintain a red color as an improvement over conventional high oxygen modified atmosphere meat packages or low oxygen with oxygen scavenger packages for sale/consumption. Sorheim et al. teach 0.3-0.5% CO, along with 60-70% CO<sub>2</sub>, 30-40% N<sub>2</sub>, and 0% O<sub>2</sub> to form carboxymyoglobin from oxymyoglobin wherein the oxygen is removed from the package so that initially the level is less than 0.5% and within 2-3 days it is about zero (Page 157, 2.2 on 158, Table 1 on page 160, 4.3 on Page 163).

30. Woodruff et al. also teach adding 0.1-1.5% CO to extend the red color on meat by forming carboxymyoglobin on the meat surface (Column 1, line 63 to Column 2, line 10, Column 10, line 50 to Column 3 line 5, Column 4, line 4-24).

31. Therefore, it would have been obvious to modify the method of DelDuca et al. and include carbon monoxide less than 0.8%, since Sorheim and Woodruff et al. teach adding this level of carbon monoxide will extend the desirable red color of raw meat during storage. One would have been substituting one conventional modified atmosphere for another for the same purpose: storing meat in a modified atmosphere wherein at the point of sale the meat is red in color.

**Declaration filed under 37 CFR 1.132**

32. The Declaration filed under 37 CFR 1.132 filed September 8, 2003 is insufficient to overcome the rejection of claims 1-37 as set forth in the last Office action because:

33. (1) The Declaration refers to the FDA regulatory status of applicant's invention, as compared to the conventional use of carbon monoxide in meat packages. However, patent law is independent from FDA regulatory law, as evidenced by issued patents claiming carbon monoxide with meat packages (e.g. Woodruff et al. (US 4522835) ) and the Federal Circuit: "FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws." In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing Scott v. Finney, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir.1994))."

34. (2) It refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

35. (3) It include(s) statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716.

36. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

***Response to Arguments***

37. Applicant's arguments filed September 8, 2003 have been fully considered but they are not persuasive.

38. Applicant argues that Sorheim teaches "fixing the color" of the meat and does not address allowing the meat pigment to convert to metmyoglobin in a similar fashion as fresh raw meat, as disclosed by applicant. However, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Sorheim teaches the recited modified atmosphere composition with carbon monoxide as an *improvement over conventional* high oxygen or low oxygen with oxygen scavenger mercantile packages. Although Sorheim does not add carbon monoxide for the same reason as applicant, Sorheim does teach adding carbon monoxide at the recited level to a modified atmosphere containing meat package as a way of improving *conventional* high oxygen or low oxygen with oxygen scavenger mercantile packages. Thus one would expect that Sorheim obtains the same results as applicant. Colombo and Breen et al. are relied on as evidence of *conventional* high oxygen or low oxygen with oxygen scavenger mercantile packaging methods.

39. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

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references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, applicant asserts that since carbon monoxide modified atmosphere meat packaging was not approved by the FDA at the time of the invention of Sorheim, carbon monoxide had no utility in meat packaging in the United States. As such applicant argues that there is no motivation to combine any of the secondary references with Sorheim. Applicant is reminded that patent law is independent from FDA regulatory law. This issue often is discussed with respect to the determination of pharmaceutical utility (MPEP 2107.01: Section V. ):

“FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws.” *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995) (citing *Scott v. Finney*, 34 F.3d 1058, 1063, 32 USPQ2d 1115, 1120 (Fed. Cir.1994)).

The fact that FDA approval is not a prerequisite for finding a compound useful is further evidenced by *Woodruff et al.* (US 4522835), who claimed the use of carbon monoxide with modified atmosphere meat packages prior to FDA approval. Thus, FDA approval of carbon monoxide is not relevant to the issue of obviousness.

### ***Conclusion***

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

41. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Madsen whose telephone number is (703)305-0068. The examiner can normally be reached on 7:00AM-3:30PM M-F.

43. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703)308-3959. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9310.

44. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0061.

  
MILTON I. CANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700

Robert Madsen  
Examiner  
Art Unit 1761

